Overview of TSCA Work Plan Methodology

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Public Process

- Public Process steps in development of Work Plan Methods document
  - August 2011 EPA published online Discussion Guide
    - Explained 2-step process to identify chemicals
  - September 7, 2011
    - Stakeholder meeting
    - Webinar
  - Online discussion forum open through September 21, 2011
  - Modifications based on public comment resulted in TSCA Work Plan Methods document

Methods Document

- Describes the methodology EPA used to identify work plan chemicals
- Step 1 Factors and Data Sources
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  - Step 1 Excluded Chemicals
- Step 2 Criteria
  - Hazard
  - Exposure
  - Persistence and Bioaccumulation
- Step 2 Categorizing Chemicals
  - Work Plan Chemicals
  - Potential Data Gathering Chemicals

Step 1 Factors

- Chemicals identified as potentially of concern for children's health (*e.g.*, chemicals with reproductive or developmental effects)
- Chemicals identified as neurotoxic
- Chemicals identified as persistent, bioaccumulative, and toxic
- Chemicals identified as probable or known carcinogens
- Chemicals used in children's products
- Chemicals used in consumer products
- Chemicals detected in biomonitoring programs

Step 1 Factors and Data Sources

- Known or probable carcinogen
  - IRIS Classification
    - 1986 A, B1; 1996 Known or probable, 1995/2005 Carcinogenic
  - IARC Group 1 or 2A
  - NTP Classification as Known Carcinogens
- Persistent, Bioaccumulative, Toxic Chemicals
  - TRI PBT Rule
  - Great Lakes Binational PBT
  - Canadian P, B and T (all three criteria met)
  - UNECE LRTAP POPs
  - UNEP Stockholm Convention POPs

Step 1 Factors and Data Sources

- Children's Health
  - IRIS: RfD or RfC for reproductive or developmental effects
  - NTP CERHR: Infants Any Effect, Pregnant Women Any Effect
  - California Proposition 65: Reproductive
- Neurotoxicity
  - IRIS: RfD or RfC based on neurotoxic effects
- Children's Product Use
  - 2006 IUR: Reported in products intended for use by children
  - Washington State Children's List

Step 1 Factors and Data Sources

- Biomonitoring
  - Addressed both human biomonitoring and environmental monitoring indicative of human exposure
    - NHANES
    - Drinking Water Contaminants
    - Fish Tissue Studies
- Step 1 identified 1,235 chemicals

Step 1 Excluded Chemicals

- Pesticides, drugs, radioactives
  - Statutorily excluded under TSCA
- Already the subject of an Action Plan
- Subject to regulation under development
- Complex process streams, other highly variable batches
- Polymers
- Common oils, fats, plant extracts
- Gases, naturally-occuring (only) chemicals, combustion products
- Explosive, pyrophoric, extremely reactive or corrosive
- Metals principally toxic to the environment
- Remaining 345 chemicals entered Step 2

Step 2 Criteria

- Chemicals scored using numerical algorithm based on combination of 3 characteristics
  - Hazard
  - Exposure
  - Persistence and Bioaccumulation
- Data available for all three factors
  - Chemical was binned as High, Moderate or Low
- Chemical could not be scored for hazard, or not for exposure (but high or moderate for hazard or persistence and bioaccumulation)
  - Chemical was binned for potential data gathering

Step 2 Hazard

- Highest hazard score for any single human health or environmental toxicity endpoint became chemical hazard score
- Hazard classification criteria based on *DfE Alternatives Assessment Criteria for Hazard Evaluation,* August 2011
- Score based on readily available data
  - Screening-level review
  - If high score for any endpoint, identified as high

Step 2 Hazard

- Endpoints scored as High (3) Moderate (2) or Low (1)
  - Acute Mammalian Toxicity
  - Carcinogenicity (High includes presumed, suspected, likely)
  - Mutagenicity/Genotoxicity
  - Reproductive Toxicity
  - Developmental Toxicity
  - Neurotoxicity
  - Chronic Toxicity
  - Respiratory Sensitization
  - Acute Aquatic Toxicity
  - Chronic Aquatic Toxicity

Step 2 Exposure

- Exposure Score based on combination of:
  - Use Type
    - Likelihood of potential exposures based on use
      - Consumer products: consider form, how widespread use
      - Industrial/commercial uses: consider dispersives
  - General Population and Environmental Exposure
    - Measured data in biota, environmental media
  - Release to Environment
    - Toxics Release Inventory data
    - Where no TRI, calculation using IUR/CDR production volume, number of sites, release potential from type of use

Step 2 Persistence/Bioaccumulation

- Persistence and bioaccumulation
  - Chemicals that are persistent and bioaccumulative are of particular concern because they can build up in the environment and organisms
- Used TRI and TSCA New Chemicals Program PBT criteria for ranking each factor separately
- Where no data, used EPI Suite 4.10 estimate
- Individual P and B scores were summed, then normalized to generate a P/B score (3, 2, 1)

Step 2 Categorizing Chemicals

- Normalized Hazard, Exposure and P/B scores were summed
  - High: 7 to 9
  - Moderate: 4 to 6
  - Low: 1 to 3
- Work Plan Chemicals are chemicals that scored high
  - 83 chemicals
- Chemicals that could not be scored were classified as Potential Data Gathering Candidate
  - 45 chemicals

2014 Update to Work Plan Chemicals List

- In 2014, EPA updated the TSCA Work Plan
- Using same methodology with newer data received as part of the Chemical Data Reporting Rule and the Toxics Release Inventory
  - Production volume and uses of some chemicals have changed
- Screened the 345 chemicals identified in 2012, the Action Plan chemicals, and several flame retardants

2014 Update to Work Plan Chemicals List

- Changes to the Work Plan chemicals identified in 2012:
  - 15 chemicals removed (Most no longer in production)
  - 1 chemical consolidated into a category
  - 23 chemicals added
  - 10 had ‘moderate’ score before; now have ‘high’ score generally based on new exposure information
  - 13 were chemicals screened for the first time
- Chemicals that scored high in 2014
  - 90 Work Plan chemicals

Thank you!